

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D2198818	<b>(X3) Date Survey Completed</b> 07/02/2021
<b>Name of Provider or Supplier</b> Residence Senior Living	<b>Street Address, City, State</b> # 1310 Dalmacia St Puerto Nuevo, San Juan, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Covid 19 Ag testing records and facility director interview on July 2, 2021 at 10:00 a.m., it was determined that the laboratory failed to follow manufacturer's instructions for storage, stability and quality control when 54 out of 54 patient's specimens were testing for Covid 19 Ag from January 4, 2021 to June 18, 2021 by BinaxNow COVID-19Ag method. The findings include : 1. The Residence Senior Living performed Covid 19Ag tests from January 4, 2021 to June 18, 2021 by BinaxNow COVID-19Ag method. 2. The BinaxNow COVID-19Ag instructions for user establishes the following: a. Store kit at 2-30 C. b. The BinaxNow COVID-19Ag Card kit is stable until the expiration date marked. c. For Quality Control requires a daily procedural control and a positive and negative external controls once each new shipment received. 3. On July 2, 2021 at 10:00 a.m., the Covid 19 Ag testing records showed that the facility did not document the expiration date of the BinaxNow COVID-19Ag Kit not the quality control procedures. Also the facility did not monitor the room temperature where the BinaxNow COVID-19Ag kit was stored. 4. The Residence Senior Living director confirmed on July 2, 2021 at 10:00 a.m., that the facility did not document the kit storage temperature, kit expiration date not the procedural controls. She stated that the manufacturer instructions for the test procedure and for the results interpretation were followed. 5. The Residence Senior Living performed 54 out of 54 patient's specimens for Covid 19Ag tests from January 4, 2021 to June 18, 2021 by BinaxNow COVID-19Ag method</p>
<b>D1002</b>	<b>REPORTING OF SARS-CoV-2 TEST RESULTS</b>

During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on Covid 19 Antigen testing records review and interview with the facility director on July 2, 2021 at 10:00 a.m., it was determined that the facility did not report the patient's test results, to any federal not state Puerto Rico Department of Health (PRDOH) entity since January 4, 2021. The findings include: 1. The facility is a Residence Senior Living that performed Covid 19Ag tests from January 4, 2021 to June 18, 2021 by BinaxNow COVID-19Ag method. 2. On July 2, 2021 at 10:00 a.m., the Covid 19 Ag testing records showed that the facility performed 54 patients specimens for Covid 19Ag tests from January 4, 2021 to June 18, 2021. 3. The PRDOH implemented the online platform, known as "Bioportal" as an electronic tool to be use by all testing facilities. The testing facility are required to report all the patient's test results. Registration to the Bioportal site is required also. 4. The Residence Senior Living director confirmed on July 2, 2021 at 10:00 a.m. that the Covid-19Ag results were not sent to the Bioportal platform, not to any federal entity. 5. The facility did not report the Covid 19 Ag results as required for 19 of 19 days from January 4, 2021 to June 18, 2021. 6. The facility did not have a Bioportal registration record evidence.